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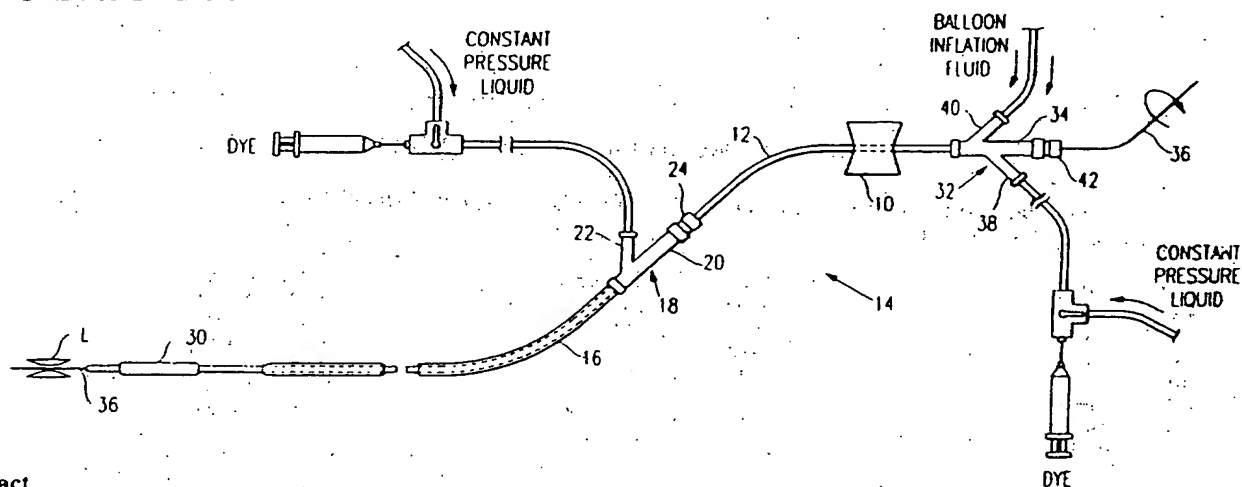
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(54) Title: MAGNETIC GUIDEWIRE ANCHORING APPARATUS AND METHOD FOR FACILITATING EXCHANGE OF AN OVER-THE-WIRE CATHETER



(57) Abstract

A magnetic guidewire anchoring apparatus for deterring longitudinal movement of a guidewire during manipulation or exchange of an over-the-wire catheter. The magnetic guidewire anchoring apparatus may comprise permanent magnet(s) or electromagnet(s), and may incorporate configuration attributes and/or attendant mounting brackets or other apparatus to facilitate positioning of the apparatus on the outer surface of a catheter through which a guidewire extends.

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5 MAGNETIC GUIDEWIRE ANCHORING APPARATUS AND METHOD FOR
FACILITATING EXCHANGE OF AN OVER-THE-WIRE CATHETER

Field of the Invention

10 The present invention pertains generally to medical equipment and, more particularly, to a magnetic apparatus for supporting a guidewire during exchange of an over-the-wire catheter.

Background of the Invention

15 Percutaneous Transluminal Angioplasty Procedures are commonly utilized in clinical practice as methods for treating vascular obstructions. In particular, coronary angioplasty procedures have become widely utilized for restoring patency to obstructed or partially obstructed coronary arteries.

20 At present, two general types of balloon angioplasty catheters are utilized in clinical practice - - The "full length over-the-wire" catheter and the "monorail" catheter.

i. Monorail Catheters

25 In a "monorail" style of angioplasty catheter, a guidewire lumen extends through only a distal portion of the catheter, typically from a distal tip aperture to a proximal aperture formed in the side wall of the catheter body. Accordingly, as the catheter is advanced over the
30 prepositioned guidewire, the proximal end of the guidewire will emerge from the side wall aperture such that the proximal portion of the guidewire remains outside of the catheter body as the catheter is advanced to its desired operative site. If it becomes necessary or desirable to
35 exchange the balloon dilation catheter, the proximally exposed portion of the guidewire can be manually held and

stabilized by the operator while the first catheter is removed and a second catheter is slid over the pre-positioned guidewire. Since the length of the catheter that must be passed over the guidewire is lessened in the "monorail" type of arrangement, it is typically easier for the operator to manually stabilize the guidewire during the exchange procedure and the need for a proximal extension or excessively long guidewire is eliminated.

10 ii. Over-the-Wire Catheters

The "over-the-wire" style of angioplasty catheter incorporates, a guidewire lumen which extends substantially through the entire length of the catheter. The guidewire lumen is separate from the balloon inflation lumen.

15

 iii. Typical Methods for Catheter Exchange During Percutaneous Transluminal Angioplasty Procedures

In a typical balloon angioplasty procedure, a guidewire is percutaneously inserted and advanced through the vasculature to a point where the distal end of the guidewire is adjacent, or has passed through, the stenotic lesion or other obstruction to be treated. Thereafter, the balloon dilation catheter is advanced over the prepositioned guidewire until the balloon is across the stenotic lesion or obstruction. Subsequent inflation of the balloon then effects dilation of the stenotic lesion or obstruction. If, during the angioplasty procedure, it becomes necessary or desirable to remove the full length over-the-wire catheter and replace it with another full length over-the-wire catheter, it is typically necessary to attach an extension on the proximal end of the guidewire (or to use an excessively long guidewire) so that a sufficient length of guidewire extends outside of the body to allow the operator to maintain a manual grasp and stabilization of the guidewire while one catheter is

35

removed and the other catheter is subsequently inserted. Inadvertent longitudinal retraction of the guidewire during the catheter exchange procedure is undesirable because subsequent re-advancement of the guidewire through the stenotic lesion may be complicated due to breakage or collapse of the obstructive matter and/or the occurrence of vasospasm.

Because the exchange of an over-the-wire catheter requires the use of an excessively long guidewire, or a proximal guide extension, and in view of the attendant cumbersomeness of effecting such exchange of an over-the-wire type of catheter, there exists a need in the art for improved methods and apparatus for stabilizing and holding a prepositioned guidewire during the exchange of an over-the-wire type of catheter.

Summary of the Invention

The present invention provides a magnetic guidewire stabilizing apparatus for preventing or minimizing longitudinal movement of a prepositioned cardiovascular guidewire. The magnetic guidewire stabilizing apparatus of the present invention is useable to prevent inadvertent retraction of the guidewire while exchanging on over the wire catheter for another.

In accordance with the invention, the magnetic guidewire stabilizing apparatus may comprise an apparatus which is separately positionable on, or close to a catheter or guidewire. Alternatively the magnetic apparatus may be integrated into the body and/or proximal connector of a catheter to facilitate magnetic holding of a guidewire which passes through the catheter.

Further in accordance with the invention there is provided a method for exchanging an over-the-wire type of catheter by applying a magnetic field to prevent or deter longitudinal movement of the guidewire during the catheter exchange procedure.

Brief Description of the Drawings

Figure 1 is a schematic diagram of a typical balloon angioplasty system having a magnetic guidewire anchoring apparatus of the present invention operatively positioned thereon.

Figure 2 is an enlarged view of a portion of the balloon angioplasty catheter shown in Figure 1, including a magnetic guidewire anchoring apparatus of the present invention positioned thereon.

Figure 3 is a diagram of a human body showing a typical percutaneous coronary artery catheterization route.

Figure 4a is a diagram of a human aortic arch, showing a balloon angioplasty catheter system, including a guidewire, positioned within a coronary artery.

Figure 4b is an enlarged view of a portion of Figure 4a.

Figure 5 is a schematic showing of an alternative electromagnetic apparatus of the present invention.

Figure 6 is a schematic showing of an alternative alternating pole magnetic apparatus of the present invention.

Figure 7 is a schematic showing of an alternative multiple magnet guidewire anchoring apparatus of the present invention.

Figure 8 is an elevational view of a "C" shaped magnetic guidewire anchoring apparatus of the present invention operatively positioned on a catheter having a guidewire extending therethrough.

Figure 8a is an elevational view of the "C" shaped magnetic guidewire anchoring apparatus of Figure 8, with the catheter removed therefrom.

Figure 9 is an elevational view of an alternative hinged magnetic guidewire anchoring apparatus of the present invention.

Detailed Description of the Preferred Embodiments

The following detailed description in the accompanying drawings are provided for purposes of describing and illustrating presently preferred embodiments of the invention only, and are not intended to limit the scope of the invention in any way.

Figure 1 shows a magnetic guidewire holding apparatus 10 of the present invention operatively positioned on an over-the-wire balloon angioplasty catheter 12. The catheter 12 is shown in conjunction with a typical balloon angioplasty system 14.

As shown, the overall balloon angioplasty system 14 comprises a tubular guiding catheter 16 having a Y-adaptor 18 formed on the proximal end thereof. The Y-adaptor 18 includes a first furcation 20 through which the balloon catheter 12 is passed and a second furcation 22 through which fluids (e.g., radiographic contrast medium, saline flush) may be infused through the lumen of the guide catheter 16. A valving/gripping apparatus 24 is provided on the proximal end of the first furcation 20. Such valving/gripping apparatus 24 may be tightened about the outer surface of the balloon catheter 12 to hold the balloon catheter 12 in a fixed position following insertion thereof. Such valving apparatus 24 may be of the type commercially available as product nos. 1905017A and/or 190501A from Medical Disposables International, West Conshocken, PA.

The balloon catheter 12 comprises an elongate catheter body having a dilation balloon 30 formed near the distal end thereof. A trifurcated adaptor 32 is formed on the proximal end of the balloon catheter 12. Such trifurcated adaptor 32 comprises a first furcation 34 through which a guidewire 36 may be passed, a second furcation 38 through which fluid (e.g., radiographic contrast medium, saline flush) may be infused and a third furcation 40 through which balloon inflation fluid may be infused. A second

valving/gripping apparatus 42 is provided on the first furcation. Such second valving/gripping apparatus may also be of the type commercially available as product nos. 1905017A and/or 190501A from Medical Disposables International, West Conshocken, PA. Such valving apparatus 42 may be tightened about the outer surface of the guidewire 36 to hold the guidewire in a fixed position relative to the balloon catheter 12.

The typical balloon catheter system 14 shown in Figure 4 may be utilized in accordance with standard clinical protocols for balloon angioplasty. In accordance with one such typical protocol, the guidewire 36 may be initially inserted into the vasculature, through a percutaneous introducer positioned within the femoral artery or other peripheral artery. Thereafter, as shown in Figures 3-4b, the guidewire 36 may be advanced through the aorta to a point where the distal end of the guidewire is positioned near the coronary ostia. Thereafter, the proximal end PE of the guidewire 36 may be inserted into the distal end of the guide catheter 16, and the guide catheter 16 may be advanced over the previously inserted guidewire 36. The guide catheter 16 is maneuvered into its desired position whereat the distal end of the guide catheter 16 is positioned within or adjacent the desired coronary ostium. Thereafter, the guidewire 36 may be further advanced through the lesion L to be treated. Thereafter, the proximal end PE of the guidewire 36 may be inserted into the distal end of the balloon catheter 12, and the balloon catheter 12 may then be advanced over the guidewire 36 to a point where the distal end of the balloon catheter 12 is adjacent the lesion L to be treated. The balloon catheter 12 is then carefully advanced to a position where the balloon 30 extends across the lesion L and the balloon 30 is inflated by passing balloon inflation fluid through the third furcation 40 of the balloon catheter 12 so as to inflate the dilation balloon 30, thereby dilating the

lesion L. Thereafter, the guidewire 36, balloon catheter 12 and guiding catheter 16 may be retracted and removed from the patient PT. If, during the performance of the balloon angioplasty procedure, it is desired to anchor the balloon catheter 12 in a desired position relative to the guiding catheter 16, such may be done by tightening the valving apparatus 24 on the proximal end of the guiding catheter 16. Similarly, if it is desired to anchor the balloon catheter 12 relative to the guidewire 36, such may be accomplished by tightening the valving apparatus 42 on the proximal end of the balloon catheter 12.

Sometimes, during the performance of endovascular catheter-mediated procedures, such as the above-described balloon angioplasty procedure, it may be desirable to effect a "catheter exchange" whereby one of the catheters is removed and replaced with a different catheter prior to completion of the procedure. The need to perform such "catheter exchange" may arise in balloon angioplasty procedures if the balloon catheter 12 is not sized or configured such that the balloon 30 may be easily passed across the lesion L.

Effecting catheter exchange during an endovascular procedure may be complicated by the fact that it may be undesirable to move the guidewire 36 after it has been properly positioned within the lesion L or elsewhere. Recognizing this concern, others have attempted to devise methods for holding the guidewire 36 in place while a catheter, such as the balloon catheter 12, is removed and replaced. Prior art devices which have been utilized to facilitate such exchange of a balloon catheter 12 include a guidewire extension which may be coupled to the proximal PE of the guidewire 36 to provide an extension which is longer than the overall length of the balloon catheter 12 to be removed. By such arrangement, the operator may continually stabilize the guidewire 36 by grasping an exposed portion of the attached guidewire extension while

the balloon catheter 12 is proximally retracted. After the distal end of the balloon catheter 12 has emerged from the proximal Y-adaptor 18 of the guiding catheter 16, the operator may then grasp an exposed portion of the guidewire 36 between the distal end of the balloon catheter 12 and the proximal end of the proximal Y-adaptor 18 of the guide catheter 16. Thereafter, first balloon catheter 12 may be proximally retracted off of the guidewire 36 and guidewire extension. Thereafter, a replacement guide catheter must be advanced over the guidewire 36 and guidewire extension, with the operator endeavoring to maintain a manual grasp of the guidewire 36 and/or guidewire extension so as to prevent inadvertent longitudinal movement of the guidewire 36.

The magnetic guidewire anchoring apparatus 10 of the present invention eliminates the need for a guidewire extension, or for manual grasping of the guidewire 36 while exchanging the balloon catheter 12. In this regard, the magnetic guidewire anchoring apparatus 10 is positioned adjacent the outer surface of the balloon catheter 12 or guide catheter 16 such that the magnet field created by the magnetic apparatus 10 will engage the guidewire 36 within the catheter 12 or 16 so as to effectively hold the guidewire 36 in a substantially fixed longitudinal position while the catheter 12 or 16 is retracted, and a replacement catheter is advanced over the guidewire 36.

It will be appreciated that the magnetic guidewire anchoring apparatus 10 of the present invention may be configured and constructed in various different ways, utilizing either permanent magnet(s) or electromagnet(s) or combinations thereof.

The basic embodiment of the magnetic guidewire anchoring apparatus 10 shown in Figure 2 is depicted as a simple permanent magnet having positive poles positioned on one side of the catheter 12 and negative poles positioned on the opposite side of the side of the catheter 12.

Alternative embodiments may incorporate pluralities of individual magnets, alternating magnetic polarities, and/or electromagnets as shown in Figures 5-7 and described herebelow. Also, the apparatus 10 may be constructed, 5 configured, and equipped to facilitate clipping, clamping, snap-fitting, bracketing, or holding of the apparatus 10 on a catheter, as shown in Figures 8-9 and described herebelow.

In any embodiment of the invention, it will be 10 appreciated that the magnetic guidewire anchoring apparatus 10 may be in the form of a single magnet which is configured so as to bend or wrap around the catheter 12, thereby enabling opposite poles of the magnet to be positioned on opposite side of the catheter 12 as shown in 15 Figure 2. Alternatively, the magnetic apparatus 10 may be formed of separate magnets (e.g., bar magnets) positioned on opposite sides of the catheter 12 such that opposite poles of the separate magnets are aligned in the manner shown in Figure 2.

20 Figure 5 shows an alternative embodiment of the magnetic guidewire anchoring apparatus 10a wherein the apparatus is made up of one or more electromagnets. Such electromagnet(s) are connected to one or more power source(s) 50a, 50b. Such power source(s) 50a 50b may be 25 volitionally actuated and deactuated by the operator to cause the magnetic field created by the apparatus 10a to turn on and off as needed.

Figure 6 shows another alternative embodiment of the magnetic guidewire anchoring apparatus 10b wherein the 30 magnet or magnets positioned on opposite sides of the catheter 12 have alternating regions of differing polarity. V-shaped notches 52 are formed in the opposing surfaces of the magnet(s) 10b, separating the regions of alternating polarity thereon. The magnet(s) 10b is/are positioned 35 adjacent the outer surface of the catheter 12 such that opposite magnetic poles are aligned directly across from

one another, thereby creating discrete lines of magnetic flux or magnetic fields running in opposite directions through the body of the catheter 12 and acting upon the guidewire 36.

5 Figure 7 shows another alternative embodiment of a magnetic guidewire anchoring apparatus 10c wherein multiple individual magnets are arranged at spaced-apart locations on opposite sides of the outer surface of the catheter 12, thereby creating separate magnetic flux lines or magnetic
10 fields which extend through the catheter 12 and act upon the guidewire 36.

Also shown in Figure 7, in accordance with the present invention, the guidewire 36a may be provided with localized regions or segments 54 having greater ferromagnetic
15 properties than the remainder of the guidewire 36a. For example, if the guidewire 36a is formed of non-ferromagnetic material, a ferromagnetic metal core or metal foil wrapping may be disposed on the guidewire 36a in the localized regions or segments 54 wherein the ferromagnetic
20 activity is to be present. By such arrangement, the magnetic guidewire anchoring apparatus 10c will act only upon the localized regions or segments 54 of the guidewire 36a having the ferromagnetic material disposed therein or thereon. Similarly, in embodiments wherein the guidewire
25 36a is formed of ferromagnetic material, the localized regions or segments 54 may contain additional or excess ferromagnetic material, or may be formed of excess mass or density relative to the remainder of the guidewire 36a, thereby enhancing the ferromagnetic properties of the
30 guidewire 36a within the localized regions or segments 54 thereof. By such arrangement, the magnetic guidewire anchoring apparatus 10c will have enhanced guidewire stabilizing effects when aligned with and acting upon the localized segments or regions 54 of enhanced ferromagnetic
35 properties.

Figure 8 shows an example of a magnetic guidewire anchoring apparatus 10d of the present invention having a "C" shaped configuration such that the opposite ends 56a 56b of the magnetic apparatus 10d may be positioned on opposite sides of the catheter 12. Also, in the embodiment shown, the opposite ends 56a, 56b of the magnetic apparatus 10d have radial depressions or cut-out regions formed therein, and are specifically spaced apart such that a catheter 12 of known diameter may be snap-fit into the opposing radial depressions or cut-out regions formed on the opposite surfaces of the C-shaped magnetic apparatus 10d. The manner in which the catheter 12 may be snap fit into the magnetic guidewire anchoring apparatus 10d is specifically shown in Figure 8.

Figure 9 shows another alternative embodiment of a magnetic guidewire anchoring apparatus 10e of the present invention, wherein the apparatus 10e has a "C" shaped configuration similar to that shown in Figures 8-8a, but wherein the apparatus 10e is transacted directly opposite the space wherein the catheter (not shown) is positioned and a hinge or bending member 58 is positioned on the body of the apparatus 10e so as to permit one or both of the opposing portions of the apparatus 10e to be bendably or pivotally moved, as shown. In this manner, the apparatus 10e may be pivotally or bendably closed about the outer surface of a catheter, irrespective of the outer diameter of the catheter. Also, as shown in Figure 9, the apparatus 10 of the present invention may further incorporate a closure apparatus 60, such as a wing nut capable of securely tightening and holding the apparatus 10e about the outer surface of the catheter (not shown).

Although the magnetic guidewire anchoring apparatus 10 of the present invention has been described herein with reference to certain specific embodiments of the invention, it will be appreciated that various modifications, changes, deletions and alterations may be made to the herein

described embodiments without departing from the intended spirit and scope of the invention. It is intended that all such foreseeable modifications, deletions, additions and alterations be included within the scope of the following

5 claims.

WHAT IS CLAIMED IS:

1. A method for deterring longitudinal movement of a guidewire during exchange of a first over-the-wire catheter through which said guidewire extends, said method
5 comprising the steps of:
 - a. providing a guidewire having at least one ferromagnetic region thereon;
 - b. applying a magnetic field through said catheter such that said magnetic field will act on a
10 ferromagnetic portion of said guidewire to magnetically deter longitudinal movement of said guidewire;
 - c. withdrawing and removing the first catheter;
 - d. passing a second catheter over said
15 guidewire.
2. The method of Claim 1 wherein step a., comprises:
positioning a permanent magnet adjacent an exteriorized portion of the catheter through which said guidewire extends.
- 20 3. The method of Claim 1 wherein step a., comprises:
positioning an electromagnet adjacent an exteriorized portion of the catheter through which said guidewire extends.
- 25 4. The method of Claim 1 wherein step a., comprises:
positioning a first magnet having a first magnetic polarity on one side of said guidewire and positioning a second magnet having a second magnetic polarity on an opposite side of said guidewire said first and second magnets being aligned with one
30 another such that at least one magnetic field will be created between said first and second magnets to deter longitudinal movement of said guidewire.

5. The method of Claim 4 wherein step a., further comprises:

positioning a first magnet having regions of alternating polarities thereon on one side of said catheter;

positioning a said second magnet having regions of alternating polarity thereon on an opposite side of said catheter;

aligning said first and second magnets such that magnetic fields will be created between regions of differing polarity on said first and second magnets.

6. The method of Claim 1 further comprising the step of:

modifying the magnetic properties of the guidewire, in at least one region thereof, so as to enhance the magnitude of magnetic attraction between said magnet and said guidewire.

7. The method of Claim 6 wherein the step of modifying the magnetic properties of said guidewire comprises:

increasing the mass of said guidewire in the region or regions to which said magnetic field is applied.

8. The method of Claim 6 wherein the step of modifying the magnetic properties of said guidewire comprises:

increasing the ferromagnetic density of said guidewire in the region or regions to which said magnetic field is applied.

9. A magnetic apparatus for deterring longitudinal movement of a guidewire formed at least partially of ferromagnetic material, during exchange of an over-the-wire cardiovascular catheter through which said guidewire extends, said apparatus comprising:

a magnet positionable adjacent at least a portion of the catheter so as to exert a magnet field through said catheter to act on said guidewire to deter longitudinal movement thereof.

10. The apparatus of Claim 9 wherein said magnet comprises a permanent magnet.

11. The apparatus of Claim 9 wherein the magnet comprises an electromagnet.

5 12. The apparatus of Claim 10 wherein said apparatus further comprises a holding apparatus for mounting said magnet in an operative position adjacent said catheter.

13. A magnetic system for deterring longitudinal movement of a ferromagnetic guidewire during exchange of an over-
10 the-wire cardiovascular catheter, said system comprising: the magnetic apparatus of Claim 9, and;

15 a region of enhanced ferromagnetic properties formed on said guidewire to enhance the magnitude of magnetic attraction between said magnet and said guidewire.

14. The system of Claim 13 wherein said region of enhanced ferromagnetic properties comprises at lease one region wherein the ferromagnetic mass of said guidewire, per unit of length, is greater than the ferromagnetic mass per unit
20 of length covers the remainder of said guidewire.

15. The system of Claim 13 wherein said region of enhanced ferromagnetic properties comprises at lease one region wherein the ferromagnetic density of said guidewire, per unit of length, is greater than the ferromagnetic density
25 per unit of length covers the remainder of said guidewire.

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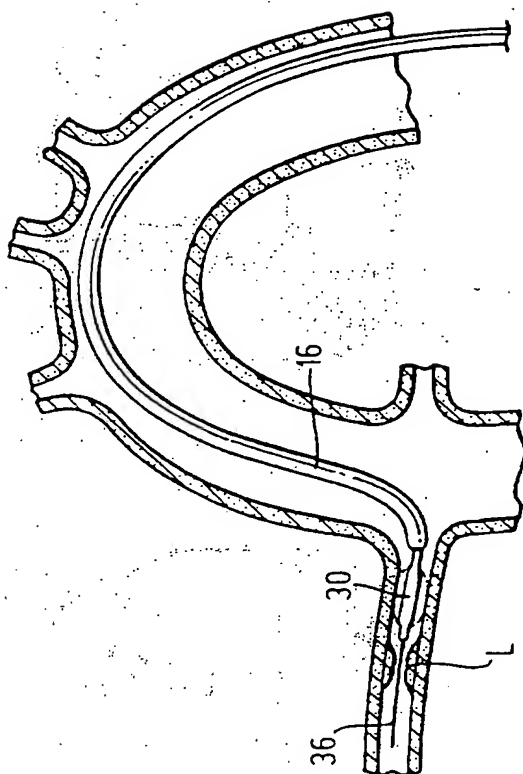


FIG. 4a

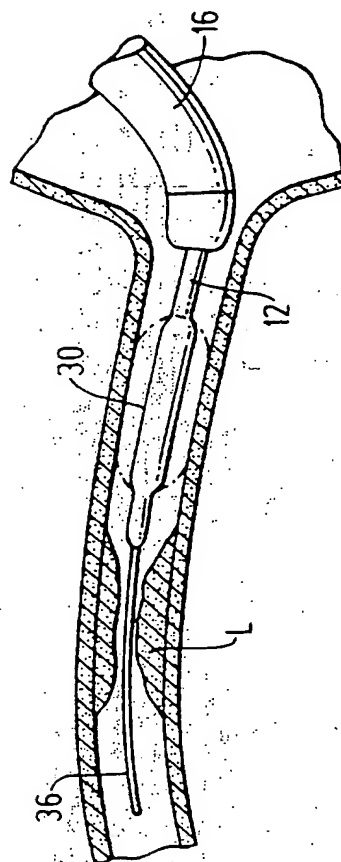


FIG. 4b

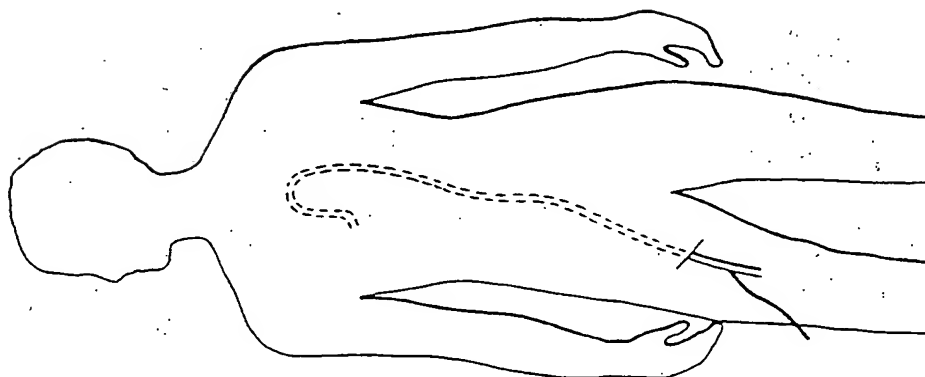


FIG. 3

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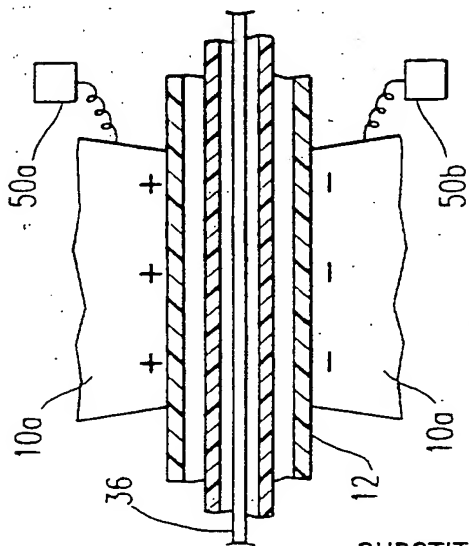


FIG. 5

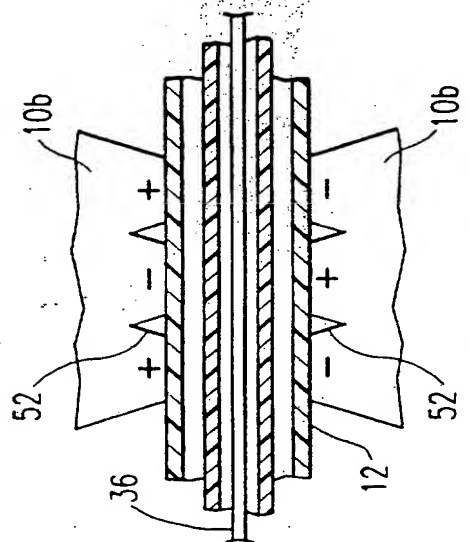


FIG. 6

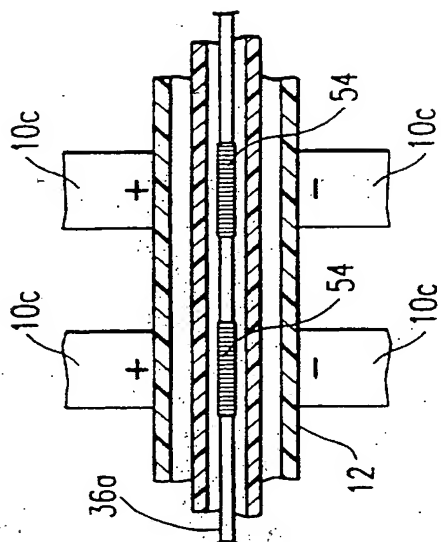


FIG. 7

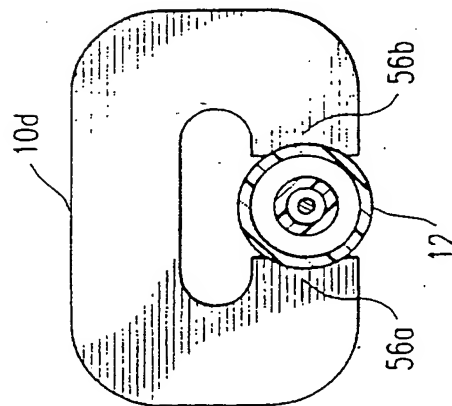


FIG. 8

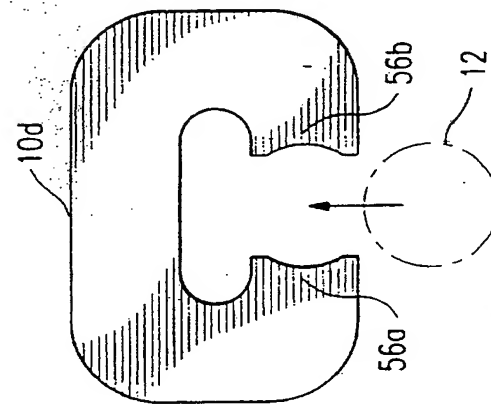


FIG. 8A

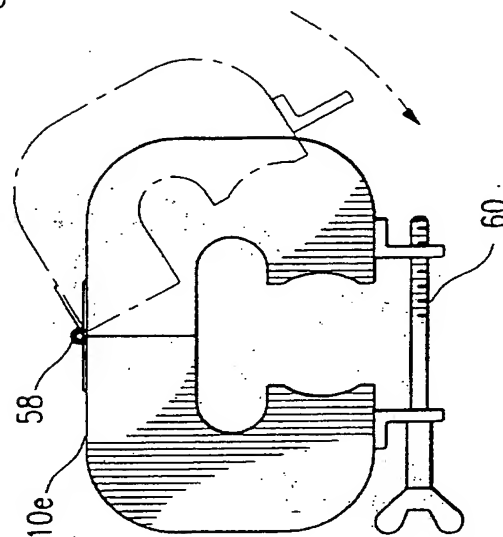


FIG. 9

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INTERNATIONAL SEARCH REPORT

Inten Application No
PCT/ 96/00468

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A,5 269 759 (HERNANDEZ ET AL.) 14 December 1993 see column 4, line 65 - column 7, line 25 see figures 1-5	9-15

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

22 May 1996

Date of mailing of the international search report

06.06.96

Name and mailing address of the ISA

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Authorized officer

Schönleben, J

INTERNATIONAL SEARCH REPORT

International application No.

US 96/ 00468

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-8
because they relate to subject matter not required to be searched by this Authority, namely:
PCT Rule 39.1 (iv)
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such
an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all
searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment
of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report
covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is
restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

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